

REMARKS

The Office Action dated March 6, 2008, has been received and carefully considered. In this response, claims 1, 10, 13, 21, 22, 27, and 28 have been amended. Entry of the amendments to claims 1, 10, 13, 21, 22, 27, and 28 is respectfully requested. Reconsideration of the pending rejections in the present application is also respectfully requested based on the following remarks.<sup>1</sup>

I. THE ANTICIPATION REJECTION OF CLAIMS 1-9 AND 13-28

On pages 2-4 of the Office Action, claims 1-9 and 13-28 were rejected under 35 U.S.C. § 102(e) as being anticipated by Sevrain (U.S. Patent Application Publication No. US2003/0135216A1). This rejection is hereby respectfully traversed with amendment.

Under 35 U.S.C. § 102, the Patent Office bears the burden of presenting at least a prima facie case of anticipation. In re King, 801 F.2d 1324, 1326 (Fed. Cir. 1986). Anticipation requires that a prior art reference disclose, either expressly or under the principles of inherency, each and every element of

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<sup>1</sup> As Applicant's remarks with respect to the Examiner's rejections are sufficient to overcome these rejections, Applicant's silence as to assertions made by the Examiner in the Office Action or certain requirements that may be applicable to such rejections (e.g., assertions regarding dependent claims, whether a reference constitutes prior art, whether references are legally combinable for obviousness purposes) is not a concession by Applicant that such assertions are accurate or such requirements have been met, and Applicant reserves the right to analyze and dispute such in the future.

the claimed invention. Celeritas Tech., Ltd., v. Rockwell Int'l Corp., 150 F.3d 1354, 1361 (Fed. Cir. 1998). The prior art reference must disclose all of the claim elements arranged or combined in the same way as recited in the claim. Net MoneyIN, Inc. v. VeriSign, Inc. (CAFC Appeal No. 2007-1565) (Fed. Cir. 2008). "In addition, the prior art reference must be enabling." Akzo N.V. v. U.S. International Trade Commission, 808 F.2d 1471, 1479 (Fed. Cir. 1986), cert. denied, 482 U.S. 909 (1987). That is, the prior art reference must sufficiently describe the claimed invention so as to have placed the public in possession of it. In re Donohue, 766 F.2d 531, 533 (Fed. Cir. 1985). Such possession is effected only if one of ordinary skill in the art could have combined the disclosure in the prior art reference with his/her own knowledge to make the claimed invention. Id.

Regarding claim 1, the Examiner asserts that Sevrain discloses the claimed invention. Applicant respectfully disagrees. However, in order to forward the present application toward allowance, Applicant has amended claim 1 to more specifically define the claimed invention, and specifically those features that further differentiate the claimed invention from Sevrain, as well as the other cited references. In particular, Applicant respectfully submits that Sevrain fails to disclose, or even suggest, a vertebral stabilization assembly for stabilizing vertebrae comprising: a vertebral screw

comprising a shaft, the shaft comprising a threaded portion and an engaging portion, the threaded portion configured to threadingly engage a vertebral body of a vertebra, the engaging portion comprising a bore formed in a lateral surface of the shaft and extending only partially through the shaft; and a connecting screw comprising a first end and a second end, the first end configured to be substantially transversely received by the bore and engaged with the engaging portion of the vertebral screw within the vertebral body of the vertebra, as presently claimed. Indeed, Sevrain teaches away from such a claimed feature by explicitly disclosing a through opening 12. Applicant respectfully submits that the claimed engaging portion provides a rigid locking connection between the claimed vertebral screw and the claimed connecting screw (see paragraphs [0113]-[0116] of U.S. Patent Application Publication No. US2004/0193161A1). Such a rigid locking connection may not be achieved by the arrangement of Sevrain since the through opening 12 allows second screw 20 to be freely engaged and disengaged in first screw 10. Also, Applicant would like to point out that the Examiner suggested amending claim 1 in the manner that claim 1 has been amended in order to further overcome the teachings of Sevrain.

At this point, Applicants would like to respectfully note that, as stated in MPEP § 2131, "[a] claim is anticipated only

if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631 (Fed. Cir. 1987). Also, as stated in MPEP § 2112, "[i]n relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." Ex parte Levy, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Int. 1990) (emphasis in original). The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. In re Rijckaert, 9 F.3d 1531, 1534 (Fed. Cir. 1993).

In view of the foregoing, Applicant respectfully submits that claim 1 is allowable over Sevrain.

Regarding claims 2-9 and 27, these claims are dependent upon independent claim 1. Thus, since independent claim 1 should be allowable as discussed above, claims 2-9 and 27 should also be allowable at least by virtue of their dependency on independent claim 1. Moreover, these claims recite additional features which are not disclosed, or even suggested, by the cited references taken either alone or in combination. For example, claim 4 recites that the vertebral screw is configured

to be positioned through the vertebral body of the vertebra but not into a pedicle portion of the vertebra. Sevrain fails to disclose, or even suggest, such a feature. In fact, Sevrain teaches just the opposite by teaching that the pairs of larger/smaller screws are both positioned not just into, but through, the pedicle portion of a vertebra.

Regarding claims 13, 21, and 22, while different in overall scope, these claims recite subject matter related to claim 1. Thus, the arguments set forth above with respect to claim 1 are equally applicable to claims 13, 21, and 22. Accordingly, Applicant respectfully submits that claims 13, 21, and 22 are allowable over Sevrain for the same reasons as set forth above with respect to claim 1.

Regarding claims 14-20 and 23-28, these claims are dependent upon independent claims 13 and 22. Thus, since independent claims 13 and 22 should be allowable as discussed above, claims 14-20 and 23-28 should also be allowable at least by virtue of their dependency on independent claims 13 and 22. Moreover, these claims recite additional features which are not disclosed, or even suggested, by the cited references taken either alone or in combination. For example, claim 26 recites that the pedicle screw has a coupling portion configured to couple with a guide member, and further including a guide member configured to couple with the coupling portion of the pedicle

screw. Sevrain fails to disclose, or even suggest, such a feature.

In view of the foregoing, it is respectfully requested that the aforementioned anticipation rejection of claims 1-9 and 13-28 be withdrawn.

## II. THE OBVIOUSNESS REJECTION OF CLAIMS 10-12

On pages 3-4 of the Office Action, claims 10-12 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Sevrain (U.S. Patent Application Publication No. US2003/0135216A1). This rejection is hereby respectfully traversed.

Under 35 U.S.C. § 103, the Patent Office bears the burden of establishing a prima facie case of obviousness. In re Fine, 837 F.2d 1071, 1074 (Fed. Cir. 1988). There are four separate factual inquiries to consider in making an obviousness determination: (1) the scope and content of the prior art; (2) the level of ordinary skill in the field of the invention; (3) the differences between the claimed invention and the prior art; and (4) the existence of any objective evidence, or "secondary considerations," of non-obviousness. Graham v. John Deere Co., 383 U.S. 1, 17-18 (1966); see also KSR Int'l Co. v. Teleflex Inc., 127 S. Ct. 1727 (2007). An "expansive and flexible approach" should be applied when determining obviousness based

on a combination of prior art references. KSR, 127 S. Ct. at 1739. However, a claimed invention combining multiple known elements is not rendered obvious simply because each element was known independently in the prior art. Id. at 1741. Rather, there must still be some "reason that would have prompted" a person of ordinary skill in the art to combine the elements in the specific way that he or she did. Id.; In re Icon Health & Fitness, Inc., 496 F.3d 1374, 1380 (Fed. Cir. 2007). Also, modification of a prior art reference may be obvious only if there exists a reason that would have prompted a person of ordinary skill to make the change. KSR, 127 S. Ct. at 1740-41.

Regarding claim 10, the Examiner asserts that Sevrain discloses the claimed invention. Applicant respectfully disagrees. However, in order to forward the present application toward allowance, Applicant has amended claim 10 to more specifically define the claimed invention, and specifically those features that further differentiate the claimed invention from Sevrain, as well as the other cited references. In particular, Applicant respectfully submits that Sevrain, fails to disclose, or even suggest, a method for stabilizing vertebrae using a vertebral stabilization assembly comprising: inserting a vertebral screw into a vertebra from an anterior side of the vertebra, the vertebral screw comprising a shaft with a threaded portion configured to threadingly engage the vertebra such that

a portion of the threaded portion of the shaft engages a vertebral body portion of the vertebra, the shaft of the vertebral screw comprising an engaging portion configured to receive a connecting screw, and the shaft of the vertebral screw comprising a coupling portion configured to couple with a guide member; locating the coupling portion of the shaft of the vertebral screw from an anterior side of the vertebra; coupling the guide member to the coupling portion of the shaft of the vertebral screw from the anterior side of the vertebra; and inserting a connecting screw through the anterior side of the vertebra using the guide member while the guide member is coupled to the coupling portion of the shaft of the vertebral screw, the connecting screw comprising a first end configured to be received by and terminated at the engaging portion of the vertebral screw within the vertebral body of the vertebra, as presently claimed. Indeed, Sevrain fails to mention the use of any type of guide member that couples to a shaft of a vertebral screw, let alone a guide member that is then used to insert a connecting screw through an anterior side of a vertebra while the guide member is coupled to the coupling portion of the shaft of the vertebral screw. Also, Sevrain fails to mention the use of any type of connecting screw comprising a first end that is configured to be received by and terminated at the engaging



portion of the vertebral screw within the vertebral body of the vertebra, as presently claimed.

At this point, Applicants would like to respectfully note that, as stated in MPEP § 2143.03, to establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. In re Royka, 490 F.2d 981 (CCPA 1974). That is, "[a]ll words in a claim must be considered in judging the patentability of that claim against the prior art." In re Wilson, 424 F.2d 1382 (CCPA 1970).

In view of the foregoing, Applicants respectfully submit that claim 10 is allowable over Sevrain.

Regarding claims 11 and 12, these claims are dependent upon independent claim 10. If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. In re Fine, 837 F.2d 1071 (Fed. Cir. 1988). Thus, since independent claim 10 should be allowable as discussed above, claims 11 and 12 should also be allowable at least by virtue of their dependency on independent claim 10. Moreover, these claims recite additional features which are not disclosed, or even suggested, by the cited references taken either alone or in combination. For example, claim 12 recites that the vertebral screw is configured to be positioned through the vertebral body of the vertebra but not into a pedicle portion of the vertebra. Sevrain fails to disclose, or even suggest, such

a feature. In fact, Sevrain teaches just the opposite by teaching that the pairs of larger/smaller screws are both positioned not just into, but through, the pedicle portion of a vertebra.

In view of the foregoing, it is respectfully requested that the aforementioned obviousness rejection of claims 10-12 be withdrawn.

### III. CONCLUSION

In view of the foregoing, Applicant respectfully submits that the present application is in condition for allowance, and an early indication of the same is courteously solicited. The Examiner is respectfully requested to contact the undersigned by telephone at the below listed telephone number, in order to expedite resolution of any issues and to expedite passage of the present application to issue, if any comments, questions, or suggestions arise in connection with the present application.

To the extent necessary, a petition for an extension of time under 37 CFR § 1.136 is hereby made.

Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account No. 50-0206, and please credit any excess fees to the same deposit account.

Respectfully submitted,

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